UNITED STATES DISTRICT COURT
DISTRICT Of MASSACHUSETTS

IN RE BOSTON SCIENTIFIC CORPORATION SECURITIES LITIGATION	CIVIL ACTION NO. 05-11934-DPW

MEMORANDUM
April 27, 2010

This securities fraud class action was brought by Plaintiff Mississippi Public Employees' Retirement System ("PERS") against Boston Scientific Corporation, a publicly traded manufacturer of medical devices ("Boston Scientific" or the "Company"), and its executives (collectively, the "Defendants"). Plaintiff alleges that the Company withheld material information and made misleading statements about a medical product that was eventually recalled, thereby leading to artificial inflation of the market price of Boston Scientific stock, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a). Defendants have moved for summary judgment on all of Plaintiff's claims.

The matter was transferred to my docket upon remand from the First Circuit following reversal of Judge Tauro's grant of Defendants' motion to dismiss. *See generally Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75 (1st Cir. 2008), *rev'g In re Boston Scientific Corp. Sec. Litig.*, 490

F. Supp. 2d 142 (D. Mass. 2007). Taking advantage of the broad grant of permission under the remand order to shape discovery, *Miss. Pub. Employees' Ret. Sys.*, 523 F.3d at 79, I have allowed full development of the factual issues. I now have before me a record appropriate to determine whether the Plaintiffs can present sufficient evidence to show that their claims have merit to proceed to trial. Finding that they do not, I will grant summary judgment in favor of Defendants.

I. BACKGROUND

A. Parties

Defendant Boston Scientific is a publicly traded manufacturer and distributor of medical devices. Individual defendants include Peter M. Nicholas (Co-Founder of the Company and Chairman of the Board of Directors), James R. Tobin (Chief Executive Officer), Paul A. LaViolette (Senior Vice President and Group President of Cardiovascular), Fredericus A. Colen (Senior Vice President and Chief Technology Officer), James H. Taylor, Jr. (Senior Vice President of Corporate Operations), Paul W. Sandman (Senior Vice President, Secretary, and General Counsel), Lawrence C. Best (Senior Vice President and Chief Financial Officer), Robert G. MacLean (Vice President of Human Resources), and Stephen F. Moreci (Senior Vice President and Group President of Endosurgery) (collectively, the "Individual Defendants").

Plaintiff PERS is a Mississippi-based pension fund, which

sues on behalf of a putative class of individuals and entities, which purchased Boston Scientific stock between November 20, 2003 and July 15, 2004 (the "Class Period").

B. Factual Background

Discovery has developed a substantial evidentiary record against which to measure the merit of Plaintiff's claims as alleged in its complaint. I will recite from that record in some detail, at all points considering the evidence in the light most favorable to the Plaintiff as non-moving party.

1. The Non-US Launch of the TAXUS Stents

In 2001, the Company decided to sell a new drug-eluting coronary stent called TAXUS® Express² Paclitaxel-Eluting Coronary Stent System (the "TAXUS stent"), which would compete with a similar product manufactured by Johnson & Johnson. Coronary stents are tiny, mesh tubes used in angioplasty procedures for the treatment of coronary artery disease, i.e., clogged arteries, as an alternative to open heart surgery. The TAXUS stent was virtually identical to another of the Company's stents, the "bare metal" Express² stent,[1] except that the TAXUS stent was drug-eluted, i.e., coated with a polymer containing a drug which helped ease complications associated with stent implant. Both the Express² and the TAXUS stent were implanted in arteries using

[1] The Express² combined Express™ coronary stent and Maverick® balloon dilation catheter.

the delivery Express² catheter, on which sat a tiny balloon designed to inflate the artery and permit the stent to be inserted. TAXUS stents were first distributed outside of the United States in February 2003.

2. The PIR Team's Investigation

Beginning in 2001, the Company had received a few no-deflate complaints regarding Express² stents, suggesting that the balloons did not deflate or deflated too slowly. Due to the fact that the number of no-deflate complaints on Galway-manufactured² Express² stents increased in early 2003, the Company opened up a Product Inquiry Report ("PIR") to investigate into potential quality issues, identify "root causes," and make recommendations for corrective actions or possible field actions (e.g., recall) to the Company's Field Action Committee ("FAC").[3] Because it appeared that no-deflate affected the catheter, and because Express² and TAXUS stents were mounted on the same catheter, the PIR investigation was subsequently extended to include TAXUS stents in addition to Express² stents.

[2] The Express² stents were manufactured in Maple Grove, Minnesota, and in Galway, Ireland.

[3] At least from May 2003 through the summer of 2004, members of the FAC included Dennis Ocwieja as Chairman, Dr. Mary Russell, and Individual Defendants Fredericus A. Colen, Paul W. Sandman, and James H. Taylor, Jr.

By May 2003, the PIR team's[4] investigation determined that the no-deflate incidents were attributable to a manufacturing problem with the stents known as "focal neckdown."[5] The PIR team concluded that the root cause of the focal neckdown was a combination of two factors: (1) excessive heat at the bond of the balloon and the catheter, and (2) a subsequent excessive tensile force exerted in the area of the bond. However, the PIR team was not able at the time to ascertain definitively whether the specific tensile forces were being introduced during manufacture or in the field (i.e., by physicians). Paul Weiss, an engineer in the Quality function and leader of the no-deflate investigation, explained that "[o]ne of the early concerns we had was is there a handling issue by the physician that they could be introducing pulling forces beyond which we specify."

3. The May 2003 Corrective and Preventive Actions

As a result of its investigation, the PIR team identified several corrective and preventive actions to improve the quality of the Galway devices, including (1) using only Maple Grove-manufactured distal outers, which had been determined to be more

[4] The PIR team included eight engineering and quality control professionals from Maple Grove and Galway manufacturing plants in the Quality Assurance, Regulatory Affairs, and Clinical functions.

[5] "Focal neckdown" (or "focal necking") can result when the distal outer becomes elongated, or stretched, thereby impeding the withdrawal of the contrast fluid that had been used to inflate the balloon.

robust and less susceptible to focal neckdown than Galway-manufactured distal outers,(2) lowering the temperature on the laser and improving a mechanism for aligning the laser more precisely, and finally (3) eliminating to the extent possible all potential sources of tensile that could be identified.

The Company implemented these corrective and preventive actions in April and May 2003. Specifically, the Company's decision to cease using Galway-produced distal outers in the manufacture of TAXUS and Express² stents was implemented on May 12, 2003.

4. The PIR Team's Recommendations

In a May 23, 2003 report, the PIR team recorded twenty-one no-deflate complaints on Galway Express² stents, and one no-deflate complaint on the Express² stents manufactured in Maple Grove. None of these complaints related to TAXUS stents (which at the time were manufactured only in Galway). As of a result of these incidents, the PIR team discussed whether any field action should be taken, in particular whether to recall the Express² products that had been manufactured in Galway prior to the implementation of the corrective and preventive actions.

Members of the PIR team ultimately concluded that "[n]o field action is recommended at this time," explaining that "[t]he low rate of occurrence combined with the limited severity observed in all but one case does not warrant a field action at

this time." The finding of "low rate of occurrence" was based on the PIR team estimate that the overall rate on Galway-manufactured devices was 69 parts per million. Similarly, the finding of "limited severity" was based on the conclusion that only three of the twenty-one no-deflate incidents resulted in what could be classified as serious injuries, and that the remaining deflates had resulted in limited health consequences for the patient.

5. The FAC's Decision Not To Recall

On May 27, 2003, the FAC, whose ultimate responsibility was to decide on any field action, met to discuss the PIR team's recommendations and consider whether a recall was warranted. Specifically, the minutes of the May 27 FAC meeting provide that:

> After discussion surrounding the events described in the PIRs, the FAC came to a decision to accept the recommendations contained therein to not institute field action at this time. This decision was based on the facts that the product in the field was within all of its established specifications, the frequency of the issues reported from the field were extremely low, and the consequences, while potentially severe in some cases are not outside those expected with this type of procedure.

During this meeting, the FAC also discussed the results of the investigation conducted by the PIR, in particular the fact that the no-deflate incidents were attributable to focal neckdown.

While the FAC declined to "take any specific actions in terms of a recall," the FAC decided to continue to monitor no-deflate complaints through bi-weekly reports. Later bi-weekly

reports disclosed that no-deflate complaints continued to be filed on Galway devices manufactured before May 2003; however, only very few no-deflate complaints were received by Boston Scientific on devices manufactured after implementation of the May 2003 actions.[6] Consequently, Paul Weiss, the leader of the no-deflate investigation, concluded on November 26, 2003 that "the interim actions have been very effective."

6. The "Six Sigma" Investigation Regarding the Laser Weld Shift

In May 2003, Boston Scientific empaneled a "six sigma"[7] team to investigate the no-deflate issue. The team was lead by Peter Delmer, an engineer in the Business Development Process Improvement Group in Galway. Delmer and his team completed their analysis in or around October 2003. Their analysis suggested that moving the location of the laser (from its position at 0.4 mm) closer to the balloon would make the bond more robust in the face of tensile forces and other factors that could lead to focal neckdown. However, Delmer explained that, "by October 2003, we had determined that there was a [] solution, but an awful lot

[6] In September 2003, the Company received its first no-deflate complaint on product built after implementation of the May 2003 actions. Between September 2003 and the US TAXUS launch on March 4, 2004, the Company received a total of approximately eight no-deflate complaints on Express², Maverick and TAXUS products manufactured after the May 2003 actions.

[7] "Six sigma" is an engineering problem-solving methodology that uses mathematics and statistics.

more work would have to be done in order to implement that solution." Consequently, additional research was conducted by a Maple Grove team led by Kevin Griffin throughout the December 2003-February 2004 time-period. In Griffin's words, the purpose for conducting additional research was to understand "if we were going to create another negative consequence if we moved to our proposed location of .8."

7. The FDA Submission Related to the Distal Outer Elongation Specification

In June 2003, Maple Grove engineers met "to discuss what additional component or full unit design specifications are needed to further ensure no focal necking occurs on Maverick/Exp. II style catheters in the future" and determined that "the most obvious specification was an elongation specification for the distal outer component." Once the testing and the validation work on this specification was concluded, the Company filed a Special PMA[8] Supplement-Changes Being Effected ("PMA-S I") with the US Food and Drug Administration (the "FDA") in October 3, 2003.

The purpose of this submission was to add an inspection protocol related to distal outer elongation for catheters used with Express² stents, an additional component specification designed to prevent focal neckdown. Specifically, PMA-S I

[8] The acronym "PMA" as used in this memorandum refers to the term "Premarket Approval."

reported that Boston Scientific had "received a small number of field complaints (approximately 0.0148% complaint rate) regarding the delivery system balloon's failure to deflate," and that "[t]hrough a recent CAPA [Corrective and Preventive Action] investigation, it has determined that the material properties of the distal outer shaft may contribute to the robustness of the proximal balloon weld."

PMA-S I was approved by the FDA on October 24, 2003, leading the Company to incorporate that improvement into its then-pending TAXUS PMA via an amendment filed on November 11, 2003.

8. The TAXUS PMA Council's Decision Not to Add "Non-Critical" Changes

Boston Scientific had established in 2003 a "TAXUS PMA Council"[9] to oversee and direct the coordination of the TAXUS PMA submission. The TAXUS PMA was filed in five separate modules submitted to the FDA between February and June 2003. The TAXUS PMA Council continued to meet throughout the summer of 2003, monitoring the PMA progress and amendments.

On October 7, 2003, the TAXUS PMA Council determined that, because additional manufacturing changes to Express[2] or TAXUS could "jeopardize" the FDA's review of the TAXUS PMA, no additional changes to TAXUS would be submitted after October 31

[9] Members of the TAXUS PMA Council included senior group of leaders in the Company, Individual Defendant Fredericus Colen as Chairman and two members of the FAC, Dennis Ocwieja and Dr. Mary Russell.

unless they were considered "critical" and approved by the Council. Specifically, the minutes of the October 7 PMA Council meeting provided:

> A large number of requested changes are coming from the bare stent and catheter manufacturing areas. All amendments critical to the US ramp should have been communicated and already scheduled for submission. Because the FDA review process for TAXUS could be jeopardized, no additional amendments will be filed after October 31 without consultation with the PMA Council.

At that time, the laser shift specification was, according to Defendants, not considered to be "critical," and its submission was therefore delayed until April 2004. In fact, Paul Weiss testified that, during the fall of 2003, he "would not have characterized th[e] laser alignment as a fix." Rather, he declared that "[i]t still was a preventative action to make the product more robust to focal necking."

9. The US Launch of TAXUS Stents

On November 20, 2003 - the first day of the Class Period, the Company issued a press release announcing that the FDA's circulatory devices panel would recommend that the FDA approve TAXUS stents for sale in the United States. In anticipation of the FDA approval of the TAXUS PMA, the Company "ramped up" the production of TAXUS stents for the US market. At that time, most of the TAXUS stents being manufactured for the US launch incorporated the May 2003 corrective actions (and the October

2003 distal outer elongation specification) and were also being cone puffed.[10]

As of November 2003, there had been only one no-deflate complaint reported on Express² stents and one no-deflate complaint on TAXUS stents, regarding stents manufactured in Galway since May 2003; in addition, three no-deflate complaints reported on Maple Grove Express² stents had been received as of that date. Members of the Company testified that they did not believe that the TAXUS devices being manufactured at that time suffered from a no-deflate manufacturing defect or would be subject to a recall. Specifically, James Tobin testified as follows:

> There had been a series of complaints about no-deflate - I want to say 20, more or less - and there were - apparently there were a series of changes made to the product, and I never really understood which of those changes had the desired effect, but the number of complaints dropped to nearly zero. So going into the TAXUS launch, we had thought we solved the problem.

On March 4, 2004, the FDA approved TAXUS stents for sale in the United States. Within the first couple of weeks following the US launch, Boston Scientific received about a dozen no-deflate complaints on TAXUS stents manufactured in Galway and in Maple Grove. The Company later received notice that a hospital

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[10] "Cone puffing" was a change introduced to TAXUS stents for the US launch to respond to complaints of stent embolization, or dislogement. Essentially, this technique consists of inflating the balloon over one end of the stent in order better to secure the stent in place.

had undertaken to "cease using [TAXUS] stent at ALL our facilities until it is determined if this is a product defect or an isolated incident."

10. The FDA Submission of the Laser Weld Shift

The design, testing and validation work regarding the laser weld shift initiated in the winter of 2003-2004 was completed in late March 2004. On April 2, 2004, Boston Scientific submitted a second Special PMA Supplement-Changes Being Effected ("PMA-S II") to the FDA requesting modifications to the TAXUS and Express[2] stents of (1) the laser shift from 0.4 mm to 0.8 mm and (2) the "addition of criteria from the minimum outer diameter ["minOD"] at the proximal weld region," and (3) the "addition of an in-process quality control test to measure the ["minOD"]." Consequently, in late April while PMA-S II was still pending, the Company instituted a "reticle" inspection[11] for the catheters, designed to measure the minOD criteria.[12]

Meanwhile, no-deflate issues on TAXUS stents were reported to the press but the Company remained confident at the end of April 2004 that the TAXUS stents performed very well based on the low complaint rate. Reflecting this confidence, on April 23,

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[11] The "reticle" inspection focused on the width of the distal outer at the laser bond; the reticle was essentially a magnification tool with guidelines to assist in measuring the bond width.

[12] Unlike the laser weld shift, the implementation of the reticle inspection did not require prior FDA approval.

2004, the New York Times reported that:

> Paul LaVioletta, senior vice president at the company, said more than 70,000 of the stents had been used in the United States since the device went on sale in March.
>
> 'We have to conclude, and I will say this with a lot of experience, that this product [Taxus stent] is performing extremely well.'

Similarly, the Boston Globe announced that:

> Boston Scientific spokesman Paul Donovan said the number of problem cases was minor relative to the 84,000 Taxus stents implanted in American patients since the FDA approved the device March 4. He said a few doctors in Europe reported similar problems when Taxus was initially approved for use there last year, but the complaints ended as doctors became more comfortable with the stents. . . .
>
> 'Our view is this product is performing very well,' he said. It's a complaint rate that's probably lower than what might be expected for a new product.'

On May 5, 2004, the FDA approved PMA-S II, and the new laser location was put in place that month for stents manufactured both in Galway and in Maple Grove plants. Despite its approval however, the FDA expressed concerns with PMA-S II, in particular with the fact that the TAXUS stents were subjected to cone puffing process during manufacture. In addition, the FDA continued to scrutinize the Medical Device Reports ("MDRs") filed by the Company.

On the day of the FDA's approval of the Company's PMA-S II, a Merrill Lynch analyst report noted that "[m]eanwhile, we continue to hear periodic rumblings concerning handling issues with the TAXUS stent in which the balloon does not totally

deflate. We continue to believe that the rate of events is very small and that this issue is highly manageable through in-service education by BSX reps."

Similarly, on May 7, 2004, the Boston Globe noted that:

> Boston Scientific called the problems [with TAXUS stents] relatively minor given the large number of TAXUS stents that have been implanted without incident, though it has continued to report a small number of both types of problems [balloon sticking to the coating of the stent or balloon failure to deflate]. The manufacturing change [in the laser bonding process] is meant to address the problems of balloons failing to deflate. . . . The company has no plans for manufacturing changes to address the other problem.

Plaintiff's expert, Chad Coffman, testified that the FDA's approval of the laser location manufacturing change was known to the market on or about May 7, 2004, and that "the market knew at that point they were responding to the no-deflate issue" in implementing the manufacturing change. A Prudential Equity Group, LLC analyst report observed on June 3, 2004 that

> . . . Boston Scientific's market share is holding steady at 70%+. Sales do not appear to have been affected by earlier reports of balloon deflation problems or polymer stickiness.
>
> . . . .
>
> The major risk that could impede achievement of our price target is failure to achieve the market share we expect. . . . Likewise, any product issue that might result in withdrawal or reduced share would be highly negative to the stock. . . .
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> . . . .
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> . . . The most significant risk is if serious, as-yet-undiscovered, adverse events were to occur with TAXUS

stents, putting this major franchise driving most of its earnings at risk.

11. The July 2 Recall

At the end of May 2004, the Company was informed that a Galway-manufactured TAXUS stent failed to deflate during surgery causing the death of the patient. This event was subsequently reported to the FDA. Meanwhile, the Company received a no-deflate complaint on TAXUS batch number 6294706 produced in Maple Grove in January 2004. Because it was the second time that a no-deflate complaint had been received for this batch, the Company requested that the devices from that lot that remained in inventory be retrieved and examined. This examination suggested the existence of four "out-of-box" failures, indicating that the devices were defective before being sent to the field. A similar examination was conducted on all remaining TAXUS devices from lots manufactured adjacent to lot number 6294706. Thereafter, Paul Weiss concluded that "the scope of recalling that one Maple Grove batch was sufficient based on the information we had at the time."

In late June 2004, the FAC directed that a single lot of Maple Grove-manufactured TAXUS devices should be recalled. The Company advised the FDA of this decision on July 1. Later that day, Galway reported that another batch presented multiple out-of-box failures, leading Boston Scientific to update the FDA that it would be recalling not one but two batches.

On July 2, 2004, the Company announced that it was voluntarily recalling two lots of TAXUS stents (a total of 200 stents). In a press release announcing the recall, the Company stated that the FDA had received reports of one death and sixteen serious injuries associated with balloon non-deflation, along with eight reports of balloon malfunction that had not caused injury. Overall, the press release also stated that "[o]f the[] 445,000 implants, the Company has confirmed a small number of complaints (30 worldwide) about TAXUS balloons that did not deflate or were slow to deflate [approximately 0.0067%]." The press release further explained that the recall was due to "characteristics . . . related to a narrowing in the area where the catheter and balloon are laser welded."

This perspective was echoed by financial analysts. For instance, a Morgan Stanley analyst report noted on the same day that:

> As a response to the 'no-deflate' problems it has seen since the U.S. launch, the company has also made two manufacturing changes in the two plants that supply the TAXUS stent. . . . That said, management does not believe that there are many more batches out there, if any, which are likely to have a higher risk of a 'no-deflate.' However, we believe that it is reasonable to expect that there could be a similar announcement over the next few months potentially pertaining to other batches with similar problems.

Similarly, Goldman Sachs indicated that:

> . . . In our opinion, the recall is a minor issue, which should have a negligible impact on the company's market position. We are not making any adjustments to our

> forecasts. In turn, we view the recall as a minor event for the company. We are maintaining our OP/N rating and would buy the shares at current levels.
>
> . . . .
>
> Based on management's comments, we believe that the issue has already been resolved and the recall is a remnant of a prior manufacturing process. . . .
>
> . . . .
>
> The company indicated that there are only 42 complaints worldwide (out of which 12 could not be replicated) about the balloon deflation issue with Taxus stent system out of the more than 445,000 stents which have been implanted worldwide, which implies an incidence rate of 0.009%. . . .

Plaintiff's expert testified that up until the July 2 recall, none of the disclosures had a statistically significant impact on the price of Boston Scientific Stock.

Following the July 2 recall, Boston Scientific continued its investigation, including examination of any devices remaining in inventory from any batch that had even a single no-deflate complaint. During the same time period, a team of engineers in Maple Grove were working to identify "at risk" inventory, including (1) using laser pixel software available in Maple Grove which recorded detailed information regarding the precise location of the laser for each batch of catheters, and (2) conducting research on cone puffing and its effect on tensile events. Regarding the latter, the team discovered that tensile forces could result if a puffed balloon cone was atypically large because the stent protection was applied on the device.

On or about July 9, another out-of-box failure was discovered.

12. The July 16, 2004 Recall

On July 16, Boston Scientific announced that it was voluntarily recalling 85,000 TAXUS stents and 11,000 Express² stents. In a press release announcing this recall, the Company acknowledged one death and eighteen serious injuries associated with balloon deflation failure in TAXUS stents as well as two deaths and twenty-five serious injuries associated with Express² stents. Nevertheless, the Company assured the public: "The Company implemented review of its manufacturing process, additional inspections, and an FDA approved modification to the manufacturing process for these products. The current and future production are not expected to experience similar balloon deflation problems." Despite the recall, Paul A. LaViolette assured the market, during a July 16 analyst conference call, that they would be able to replenish the market with the "new" TAXUS.

When trading closed on July 16, the Company stock price declined by 10.3%-or $4.17 per share loss. On that same day, Individual Defendant Nicholas reported in an email to another board member that "yes we discovered the problem and had a fix in place in advance of the events that led to the present situation - but we also knew of the problem on the level over a year ago and never looked inward at our own conduct."

Thereafter, on July 20, the Wall Street Journal announced that the FDA was treating the recalls as a "top priority" and decided to conduct audits at both Maple Grove and Galway manufacturing facilities. These audits revealed, however, no findings of any violations on the part of the Company. Additionally, on July 26, 2004, Boston Scientific reported 2Q 2004 earnings in line with expectations and stated the TAXUS recall sales reversal was $35 million instead of an expected $45 million.[13]

13. The August 5, 2004 Recall

On August 5, Boston Scientific announced that it was voluntarily recalling an additional 3,000 TAXUS stents. The press release announcing the recall stated that it was prompted by the Company's "ongoing monitoring" and noted that since the Company had "modified its manufacturing process, implemented new

[13] Defendants made other statements during the July 26-29 time period. For instance, during a July 26 conference call with analysts, Individual Defendant Paul A. LaViolette responded to concerns about TAXUS by saying, "[Y]ou are dealing with simple lag time in the marketplace conversion of newer products, not necessarily a continuation of complaints from the new issue product." At a meeting with a local hospital official on July 29, LaViolette further stated that the company had "identified and fixed the problem." In *Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp.* ("*BSC II*"), upon review of the operative complaint, the First Circuit found these statements to be arguably misleading in the context of the allegations under scrutiny in the motion to dismiss practice. 523 F.3d 75, 91-92 (1st Cir. 2008). Plaintiff does not, however, after discovery, rely on these statements in opposing summary judgment. The statements were made by LaViolette outside of the Class Period alleged in the Second Consolidated Amended Complaint.

tracking software and introduced new inspection protocols, it ha[d] not yet had any confirmed non-deflation problems caused by focal neckdown in non-recalled units."

14. Individual Defendant Stock Sales

During the Class Period, Individual Defendants sold (or gifted) shares in the Company's stock as follows: stock sales of $40.8 million by James R. Tobin, of $90.7 million by Lawrence C. Best, of $3 million by Paul A. LaViolette, of $13.9 million by Fredericus A. Colen, of $13.6 million by Stephen F. Moreci, of $24.3 million by Paul W. Sandman, $5.1 million by James H. Taylor, Jr., of $25.5 million by Robert G. MacLean, as well as the stock gift of $8.2 million by Peter M. Nicholas.

The Company's Stock Trading Policy in place as of December 2003 permitted Company insiders to sell the Company stock during limited "open windows."[14] In addition, the Company's Stock Trading Policy required that Company insiders "contact BSC's senior Vice President and General Counsel or his designee prior to making any trade for pre-clearance" in order to ensure compliance with section 16 of the Securities Exchange Act and "to determine if there are any important pending developments which

[14] "Open windows" are defined in the Company's Stock Trading Policy as periods "beginning on the third business day after the date upon which BSC's earnings for BSC's immediately preceding fiscal quarter have been publicly announced and ending on the last day of the second calendar month of the quarter in which the announcement is made."

need to be made public before the person could properly participate in the market or if BSC is engaged in a financing or other activity which may require BSC to limit trading by its employees."

C. Procedural History & Previous Proceedings

On February 15, 2006, several related securities fraud class action were consolidated into a single action, *In re Boston Scientific Corp. Sec. Litig.,* Civil Action No. 05-cv-11934-JLT (D. Mass.), before Judge Tauro. In connection with this consolidation, Judge Tauro approved PERS's motion for appointment as Lead Plaintiff. On April 17, 2006, PERS filed a Consolidated Amended Complaint, alleging Defendants had made false and misleading statements in connection with four events: (1) a Department of Justice investigation into a 1998 product recall, (2) a civil action with Medinol Ltd., (3) the 2004 recall of TAXUS stents, and (4) FDA investigations and warnings regarding the Company's manufacturing facilities.

Defendants subsequently filed a motion to dismiss the Consolidated Amended Complaint, which was granted in its entirety by Judge Tauro on June 21, 2007. *In re Boston Scientific Corp. Sec. Litig.* ("*BSC I*"), 490 F. Supp. 2d 142 (D. Mass. 2007). On April 16, 2008, the First Circuit reversed with regard to the TAXUS recall claims, the only claims as to which an appeal had been pressed, and remanded the case. *Miss. Pub. Employees' Ret.*

Sys. v. Boston Scientific Corp. (“*BSC II*”), 523 F.3d 75 (1st Cir. 2008).

On March 2, 2009, PERS filed a Second Consolidated Amended Complaint, removing allegations that had been dismissed and refining their TAXUS stent allegations in light of discovery. In this Second Consolidated Amended Complaint, PERS brings its claims on behalf of shareholders who had acquired Boston Scientific equity securities between November 20, 2003 and July 15, 2004 for violation of section 10(b) and Rule 10b-5 of the Securities Exchange Act of 1934 against all Defendants (Count I) and violation of section 20(a) of the Securities Exchange Act of 1934 against all Defendants (Count II) in connection with the TAXUS recall claims. PERS filed a motion for class certification for the Second Consolidated Amended Complaint, which I granted on March 10, 2009. *In re Boston Scientific Corp. Sec. Litig.,* 604 F. Supp. 2d 275 (D. Mass. 2009).

II. STANDARD OF REVIEW

Summary judgment is appropriate if the record shows “that there is no genuine issue as to any material fact” and that “the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). On summary judgement, “[a] genuine issue exists where a reasonable jury could resolve the point in favor of the nonmoving party.” *Estrada v. Rhode Island*, 594 F.3d 56, 62 (1st Cir. 2010) (quoting *Meuser v. Fed. Express. Corp.*, 564 F.3d 507,

515 (1st Cir. 2009)) (alteration in original) (internal quotation marks omitted). "A fact is material only if it possesses the capacity to sway the outcome of the litigation under the applicable law." *Id.* (quoting *Vineberg v. Bissonnette*, 548 F.3d 50, 56 (1st Cir. 2008)).

When assessing the merits of a motion for summary judgment, "the court must consider the record in the light most favorable to the party opposing the motion and must indulge in all inferences favorable to that party." *Evans Cabinet Corp. v. Kitchen Int'l, Inc.*, 593 F.3d 135, 140 (1st Cir. 2010). Nevertheless, "the non-moving party must put forth specific facts to support the conclusion that a triable issue subsists" in order to overcome a motion for summary judgment. *Martínez-Rodríguez v. Guevara*, 597 F.3d 414, 419 (1st Cir. 2010). "With respect to each issue on which the nonmoving party has the burden of proof at trial, that party must 'present definite, competent evidence to rebut the motion.'" *Id.* (quoting *Vineberg*, 548 F.3d at 56). Therefore, "[e]vidence that is merely colorable or is not significantly probative" will not defeat the motion. *Evans Cabinet,* 593 F.3d at 140 (quoting *Mesnick v. Gen. Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991)) (internal quotation mark omitted).

More specifically with respect to securities fraud and scienter, "[a]lthough it is unusual to grant summary judgment on scienter, summary judgment on this issue is sometimes

appropriate." *SEC v. Ficken*, 546 F.3d 45, 51 (1st Cir. 2008). "Even in cases where elusive concepts such as motive or intent are at issue, summary judgment may be appropriate if the nonmoving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation." *Id.* (quoting *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990)).

III. DISCUSSION

The crux of Plaintiff's case is that Defendants knowingly or recklessly withheld material information regarding the no-deflate risk and the prospect of recall, thereby causing the Company stock price to be inflated, harming investors and allowing the Individual Defendants to enrich themselves in excess of $225.4 million by their own trading during the Class Period.

A. Section 10(b) and Rule 10b-5 (Count I)

Plaintiff has made allegations against Defendants under section 10(b) and Rule 10b-5 thereunder. Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . , any manipulative or deceptive device or contrivance in contravention of" a securities rule. 15 U.S.C. § 78j(b). Rule 10b-5 prohibits "mak[ing] any untrue statement of a material fact or omit[ting] to state a material fact necessary in order to make the statements made, in light of the circumstances under which

they were made, not misleading." 17 C.F.R. § 240.10b-5.

To establish securities fraud under section 10(b) and Rule 10b-5 requires proof of six elements: "(1) a material misrepresentation or omission; (2) scienter; (3) connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *Day v. Staples, Inc.*, 555 F.3d 42, 56 (1st Cir. 2009) (quoting *Ezra Charitable Trust v. Tyco Int'l, Ltd.*, 466 F.3d 1, 6 (1st Cir. 2006)); *see generally Dura Pharms, Inc. v. Broudo,* 544 U.S. 336, 341-42 (2005). To support their claim that summary judgment should be granted as a matter of law, Defendants argue that Plaintiff has failed as a matter of law to satisfy three of these elements: that a misrepresentation or omission (1) was made with scienter, i.e., a wrongful state of mind, (2) was material, and (3) caused an economic loss. I will discuss these three issues in turn.

1. Scienter

Scienter refers to a "mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976). In this circuit, scienter requires "a showing of either conscious intent to defraud or a high degree of recklessness." *Ficken*, 546 F.3d at 47 (quoting *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008)) (internal quotation marks omitted). Here, Defendants argue that summary judgment is required on the element of scienter because: (a) there is no evidence that Defendants

recklessly disregarded a significant risk of no-deflate and the prospect of recall, and (b) Plaintiff's insider trading allegations cannot substitute for scienter here, thereby (c) negating any demonstration of corporate scienter.

a. Intent to Defraud or Recklessness

As a general proposition, "[k]nowingly omitting information is probative, although not determinative, of scienter." *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc. ("Biogen IDEC"),* 537 F.3d 35, 47 (1st Cir. 2008) (quoting *BSC II*, 523 F.3d at 87). "However, the fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002). In this connection, "[r]ecklessness is a highly unreasonable omission, involving not merely simple, or even inexcusable[] negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it." *Ficken*, 546 F.3d at 47-48 (quoting *SEC v. Fife*, 311 F.3d 1, 9-10 (1st Cir. 2002)) (second alteration in original) (internal quotation marks omitted).

Here, Plaintiff's main argument is that Defendants failed to disclose adverse facts regarding the Company's manufacturing of

the Express² catheter, which according to Plaintiff, led to a major recall. Specifically, Plaintiff contends that Defendants had identified a manufacturing "fix" to the no-deflate and focal neckdown problems, i.e., the laser weld shift, by October 2003 as a result of the on-going six sigma investigation. However, Plaintiff contends, Defendants "gambled" by delaying submission of the manufacturing fix until April 2004. Plaintiff's explanation as to why Defendants withheld this information is that Defendants hoped that "eventually the 'good news' post-manufacturing change batches that were 'robust' to no-deflate would subsume or minimize the complaints from the 'bad news' batches that were susceptible to no-deflate." This explanation is based on the transcript of the July 16 analyst conference call, where Defendants assured the market that they would be able to replenish the market with the "new" TAXUS.

In response, Defendants contend that, even if the manufacturing change solved the problem by preventing balloon non-deflation, it does not mean that Defendants were obliged to disclose it earlier. Essentially, Defendants contend that they did not recklessly disregard a "significant risk" of no-deflate by failing to disclose the manufacturing change which they were developing through an orderly internal product review and development process. Defendants rely on, among other cases, *Biogen IDEC* in which the First Circuit held that "[a] statement

cannot be intentionally misleading if the defendant did *not* have sufficient information at the relevant time to form an evaluation that there was a *need* to disclose certain information and to form an intent not to disclose it." 537 F.3d at 45 (emphasis added). The First Circuit in *Biogen IDEC* ultimately affirmed the district court's dismissal of a securities fraud action for failure to plead a strong inference of scienter based, *inter alia*, on the fact there was no allegation suggesting that "defendants knew of any causal relationship between the use of [a drug] and the separate opportunistic infections diagnosed for the five patients, and then intentionally withheld the data" or even "knew of a *significant* risk of . . . opportunistic infections while the FDA was reviewing [the drug application]." *Id.* at 50.

Here, unlike the defendants in *Biogen IDEC*, however, it is clear that Defendants were aware, as a result of the on-going six sigma investigation, of some potential "causal relationship" between the laser weld shift and the balloon no-deflation, i.e., the fact that this change could have the effect of reducing no-deflation incidents. As the First Circuit observed in *BSC II*, this is not "a case where there is no contemporaneous evidence at all that defendants knew earlier what they chose not to disclose until later." *BSC II*, 523 F.3d at 91. Nevertheless, as Delmer, the engineer in charge of conducting the six sigma investigation, explained, "by October 2003, we had determined that there was a

[] solution, but an awful lot more work would have to be done in order to implement that solution." As a result, further research was conducted throughout the December 2003-February 2004 time-period in order to understand whether the Company was "going to create another negative consequence" by implementing the laser weld shift. The design, testing and validation protocol was not finalized until late March 2004. The evidence of record therefore demonstrates that, in November 2003 and thereafter, the Company was not aware of a "significant risk" in delaying the submission of the change to the FDA; rather it was proceeding cautiously on the assumption that further research remained to be conducted in order to avoid any potential negative consequences that the implementation of the laser weld shift could have on the no-deflate issue.

That finding is further corroborated by the very small number of complaints reported on TAXUS stents by November 20, 2003 - the first day of the Class Period. By that time, Defendants had implemented the May 2003 corrective and preventive actions suggested by the PIR team, causing the number of no-deflate complaints to be reduced further. As of November 2003, there had been only one no-deflate complaint reported on an Express² stent and one no-deflate complaint on a TAXUS stent, which were manufactured in Galway since May 2003, and three no-deflate complaints reported on Maple Grove Express² stents. Even

Plaintiff's expert conceded that "the rate of failure did come down after the interim actions." Accordingly, the evidence of record establishes that the Defendants had good reason to believe in the fall of 2003 that the May 2003 corrective and preventive measures had been "very effective" and that the TAXUS devices being manufactured at that time did not suffer from a no-deflate manufacturing defect. Also of importance is the fact that the total number of complaints reported on TAXUS stents by the end of the Class Period remained very small, roughly 45 complaints out of approximately 500,000 stents, an incidence rate of 0.009%. There is nothing in the record to suggest this incidence rate is out of proportion sufficiently to raise red flags given the type of procedure involved.

On this record, a reasonable jury could not find that the Defendants knew of or recklessly disregarded a "significant risk" of no-deflate incidents and therefore acted with scienter in not disclosing the laser weld shift from the fall of 2003 until May 2004. Nor could a reasonable jury find that the Defendants were aware of a significant prospect for recalls until shortly before those recalls were undertaken.[15] Accordingly, I conclude, considering the record in the light most favorable to Plaintiff,

[15] Monday morning remorse, such as that expressed in Individual Defendant Peter M. Nicholas' July 16 email, and the regret that they had not done more earlier, does not establish - or even suggest - that the Defendants had knowledge or acted in reckless disregard of a meaningful prospect of recall.

that no genuine issue of material fact exists as to whether Defendants acted with scienter. I turn now to determine whether evidence of insider trading may somehow erode or modify that conclusion.[16]

b. Insider Trading

All Individuals Defendants engaged in insider trading during the Class Period. To the extent "there is reason to be concerned about material omissions or misrepresentations, the presence of insider trading can be used, in combination with the other evidence, to establish scienter." *Biogen IDEC,* 537 F.3d at 55. "Unusual trading or trading at suspicious times or in suspicious amounts by corporate insiders has long been recognized as probative of scienter." *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 197 (1st Cir. 1999). "At a minimum, the trading must be in a context where defendants have incentives to withhold material, non-public information, and it must be unusual, well beyond the normal patterns of trading by those defendants." *Id.* at 198.

I find that the evidence developed during the course of discovery provides no triable question regarding insider trading

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[16] In light of the principle that, as will be discussed in Section III.A.1.b. *infra*, "[i]nsider trading cannot establish scienter on its own, but it can only be used to do so in combination with other evidence," *BSC II,* 523 F.3d at 92, this conclusion alone warrants the grant of summary judgment to Defendants. Nonetheless, for purposes of completeness in this memorandum, I will proceed with an analysis assuming *arguendo* that the evidence is sufficient to permit the use of insider trading evidence to establish scienter.

as evidence of scienter. The record shows that, at least from December 2003, all the transactions by Individual Defendants occurred either during "open windows," i.e., periods of time during which stock sales by insiders were allowed pursuant to the Company's stock trading policy, or pursuant to Rule 10b5-1 trading plans removing control of the sales decisions to a broker. The record also shows that Individual Defendants whose deposition was taken testified that they sought pre-clearance from the legal department for their sales or the execution of their Rule 10b5-1 trading plans. Furthermore, during the Class Period, most Individual Defendants either (1) did not sell any share of the Company stock for their personal benefit but rather gifted these shares (i.e., Peter M. Nicholas), (2) increased their Company holdings (i.e., James R. Tobin, Paul A. LaViolette), (3) were not "well beyond normal sales patterns" (i.e., Fredericus A. Colen, James H. Taylor, Jr., Lawrence C. Best), or (4) occurred during a period where the no-deflate issue was reasonably believed to have been resolved (i.e., Paul W. Sandman). Finally, with respect to Robert G. MacLean, Vice-President of Human Resources, and Stephen Moreci, Senior Vice President and Group President of Endosurgery,[17] the record shows no evidence that they could have detained any non-public

[17] The Endosurgery Group manufactured and sold products for use in "non-vascular businesses" such as endoscopy and urology, not products for use in cardiology, such as TAXUS and Express² stents.

information regarding the stents. The mere fact that they were members of the Company's Executive Committee is in itself insufficient to warrant such a finding.

The evidence of record establishes that the Individual Defendants' sales (or gift) of the Company stock during the Class Period were neither unusual, nor suspicious. Consequently, I conclude that no genuine issue of material fact exists as to whether insider trading during the Class Period evidences scienter.

c. Corporate Scienter

Plaintiff argues more generally for a theory of corporate scienter that derives from the actions of the Company's agents. The concept of "corporate or (collective) scienter" has not yet been discussed in this circuit; courts in other circuits have addressed the issue at the pleading stage, but reached divergent conclusions.

On the one hand, the Second Circuit has observed that:

> In most cases, the most straightforward way to raise [an inference of scienter] for a corporate defendant will be to plead it for an individual defendant. But it is possible to raise the required inference with regard to a corporate defendant without doing so with regard to a specific individual defendant.

Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc., 531 F.3d 190, 195 (2d Cir. 2008). The Seventh Circuit reached a similar conclusion, holding that "it is possible to draw a strong inference of corporate scienter without being able

to name the individuals who concocted and disseminated the fraud." *Makor Issues & Rights, Ltd. v. Tellabs Inc.,* 513 F.3d 702, 710 (7th Cir. 2008).

Other circuits have rejected the collective scienter theory of liability. *See, e.g, Southland Sec. Corp. v. INSpire Ins. Solutions Inc.*, 365 F.3d 353, 365 (5th Cir. 2004) ("group pleading doctrine conflicts with the scienter requirement of the PSLRA" because the PSLRA requires the plaintiffs "to distinguish among those they sue and enlighten *each defendant* as to his or her particular part in the alleged fraud."); *Phillips v. Scientific-Atlanta, Inc.*, 374 F.3d 1015, 1018 (11th Cir. 2004) ("the most plausible reading [of the PSLRA] in light of congressional intent is that a plaintiff, to proceed beyond the pleading stage, must allege facts sufficiently demonstrating each defendant's state of mind regarding his or her alleged violations.").

Here, I find that the evidence contained in the record is insufficient to show either that the Company as a whole or the Individuals Defendants acted with scienter when they chose not to disclose the manufacturing change until the spring of 2004. To the contrary, the evidence demonstrates a measured effort, in furtherance of a prudently cautious approach, by a corporation seeking to understand and correct the limitations of a product and to respond with appropriate adjustments. Even viewing the evidence in the light most favorable to Plaintiff, the corporate

process evidenced in the record establishes a reasonable effort in light of developing information to address, rather than ignore, risks inherent in the launch of a product such as the TAXUS stents. Consequently, there is no sufficient evidence to support a finding of corporate scienter.

2. Materiality

Materiality requires that "the complainant must believe there is a 'likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.'" *Staples*, 555 F.3d at 57-58 (quoting *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988)). Further, "[w]hile a company need not reveal every piece of information that affects anything said before, it must disclose facts, if any, that are needed so that what was revealed [before] would not be so incomplete as to mislead." *Biogen IDEC*, 537 F.3d at 44 n.10 (quoting *In re Cabletron Sys., Inc.*, 311 F.3d 11, 36 (1st Cir. 2002)) (internal quotation marks omitted). "The existence of a material omission is usually a question for the trier of fact." *BSC II*, 523 F.3d at 87. Defendant's response to Plaintiff's allegations is two-fold, (a) the facts alleged by Plaintiff were known to the market before July 16, and (b) disclosure of these facts had no impact on the Company stock price. In making this

response, Defendants essentially raise a "truth on the market" defense.

The "truth on the market" defense "is intended to rebut the plaintiff's presumption of reliance on the market by suggesting that 'even if fraudulent statements were made in attempt to manipulate the market price of a security, if corrective information credibly entered the market and dissipated the effects of the misstatements, those who traded [defendant's] shares after the corrective statements would have no direct or indirect connection with the fraud.'" *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 36-37 (D. Mass. 1997) (quoting *Rand v. Cullinet Software, Inc.*, 847 F. Supp. 200, 205 (D. Mass. 1994)) (internal quotation marks omitted). Generally, "a truth on the market defense is intensely fact-specific." *Id.* at 37. "Nonetheless, summary judgment may be appropriate in cases involving curative disclosures where, in view of the information in the market from all sources, a reasonable jury could not conclude that any misconduct by the defendant was material." *Id.*

Here, the record establishes, and the Plaintiff's expert conceded, that the market was aware of the no-deflate complaints prior to the July 16 recall. In fact, the Company filed MDRs' for all no-deflate failures on TAXUS and Express² stents with the FDA; these were for the most part available on the FDA's website. Market awareness is further supported by financial reports and

news articles dated April 2004. In addition, it is clear that the market knew of the manufacturing "fix," at least as of May 5, the day the FDA approved the Special PMA-S adopting this "fix" and posted it online. It would have been clear to the market that the stents produced prior to May 5 did not incorporate this manufacturing change. I find no evidence that the disclosures made during the Class Period had any "material" impact on the Company stock price.

I conclude that no reasonable jury could find that any misconduct by the Defendants was material because the market had available sufficient corrective information to cure any arguably misleading statements or omissions to state material facts.

3. Loss Causation

Loss causation refers to "a causal connection between the material misrepresentation and the loss." *Dura Pharms,* 544 U.S. at 342. "Normally, in cases such as this one (i.e., fraud-on-the-market cases), an inflated purchase price will not *itself* constitute or proximately cause the relevant economic loss." *Id.* (emphasis added). As discussed in section III.A.2. *supra*, the record establishes that the market was aware, before the July 16 recall, that no-deflate complaints existed; that the Company had identified a "fix," the laser weld shift, to eliminate the problem; and that the Company had delayed the implementation of the "fix" until after the US launch of TAXUS stents. Further,

there is no evidence that Defendants were aware before the recall that cone puffing could be said to have created tensile forces. In fact, even Plaintiff's expert admitted that it was only "clearly *after* the fact it's - it became known that cone puffing could add tensile forces."

Under these circumstances, the record evidence establishes that the mere fact the Company stock price was inflated before the July 16 recall is insufficient in itself to prove that the alleged misrepresentations caused the economic loss alleged by Plaintiff.

4. Conclusion

I conclude that Plaintiff has failed to show that a genuine issue of material fact exists as to the scienter, the materiality, and the loss of causation requirements. Plaintiff cannot establish on the evidence of record before me essential elements of a Rule 10b-5 claim. Consequently, summary judgment will be entered for Defendants with respect to Count I.

B. Section 20(a) (Count II)

Plaintiff has also made allegations against Defendants under section 20(a) of the Securities Exchange Act, which establishes joint and several liability on "[e]very person who, directly or indirectly, controls any person liable" for a violation of securities fraud. 15 U.S.C. § 78t(a). However, "[t]he plain terms of section 20(a) indicate that it only creates liability

derivative of an underlying securities violation." *ACA Fin.*, 512 F.3d at 67; *see also In re Stone & Webster Sec. Litig.*, 424 F.3d 24, 27 (1st Cir. 2005) ("[I]t is an essential element of the § 20(a) controlling person claims in question that plaintiffs show a Rule 10b-5 violation by the controlled entity.").

Because I have concluded there is no underlying 10b-5 violation, the section 20(a) must fail. Consequently, summary judgment will be entered for Defendants as to Count II.

IV. CONCLUSION

For the reasons set forth more fully above, I GRANT Defendant's motion for summary judgment.

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE